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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,964	07/08/2004	Keizo Sugawara	07385.0030	3433
23280	7590	12/18/2008		
Davidson, Davidson & Kappel, LLC			EXAMINER	
485 7th Avenue			CHANG, CELIA C	
14th Floor				
New York, NY 10018			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,964

Applicant(s)

SUGASAWA ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-1/108.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7,9-13,18-20 and 22-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,7,9-13,18-20 and 22-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 9/21/04, 10/1/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

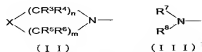
DETAILED ACTION

1. This application is a RCE of SN 10/500,964.
Claims 1-4, 6, 8, 14-17, 21 have been canceled.
Claims 5, 7, 9-13, 18-20, 22-47 are pending.
2. The rejection of claims 5, 7, 9-11 under 35 US C 102(a) over Muto et al. CA137 corresponding to published WO 02/049632 is maintained for reason of record.
Please note that, it is noted that in the two translations of the priority documents, the Markush scope of the instant claims was not embraced since elements R20, R21, R22, R23, R26, R27, or R28, are not found and the scope of these elements are not consistent with the definition of the priority documents as R3-R6. Therefore, the benefit of priority date cannot be granted and the rejection is proper.

To obviate this rejection, an affidavit by Dr. Hideki Anan was filed which stated that

“support for the numerical representation of Markush elements R²⁰, R²¹, R²², R²³, R²⁶, R²⁷, and R²⁸ recited in independent claims 5 and 37 of the present invention can be found, for example, at page 7, lines 10-20 of the English translation of the present application as filed, and at page 6, line 19 to page 7, line 8 of the Japanese priority document JP 2002-10413 (corresponding to page 8, line 18 to page 9, line 11 of the English translation of Japanese priority document JP 2002-10413) and page 6, line 19 to page 7, line 8 of the Japanese priority document JP 2002-10447 (corresponding to page 8, line 10 to page 9, line 3 of the English translation of Japanese priority document JP 2002-10447)”.

On page 8, line 10 to page 9, line 3 of the English translation of Japanese priority document JP 2002-10447 and page 8, line 18 to page 9, line 11 of the English translation of Japanese priority document JP 2002-10413 it was disclosed that:



n: an integer of 1 to 3,

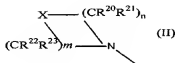
m: an integer of 1 to 2,

X: O, S, or a group represented by N(R⁹), or C(R¹⁰)(R¹¹),

R³, R⁴, R⁵, R⁶, R⁹, R¹⁰ and R¹¹: which may be identical or different, -

H: -OH; -O-lower alkyl; optionally substituted lower alkyl; optionally substituted cycloalkyl; optionally substituted aryl; optionally substituted aralkyl; optionally substituted aromatic heterocycle; optionally substituted heteroarylalkyl; optionally substituted nonaromatic heterocycle; lower alkenyl; lower alkylidene; -COOH; -COO-lower alkyl; -COO-lower alkenyl; -COO-lower alkylene-aryl; -COO-lower alkylene-aromatic heterocycle; carbamoyl or amino, each of which may be substituted with one or more groups selected from the group consisting of lower alkyl which may be substituted with halogen, -OH, -O-lower alkyl or -O-aryl, and cycloalkyl; -NHCO-lower alkyl; or, oxo, ←

The instant claim 1, p.7 is as following:



wherein the symbols have the following meanings,

n: is 2

m: is 2

(CR²⁰R²¹ and CR²²R²³ may be identical or different),

X: is a group represented by N-R³⁶ or C(R³⁷)R³⁸ C(R³⁷)R³⁸ or NR²⁶.

Each of R²⁰, R²¹, R²², R²³, R²⁶, R²⁷, or and R²⁸ is independently selected from the group consisting of -H; -OH; -O-lower alkyl; optionally a substituted or unsubstituted lower alkyl; optionally a substituted or unsubstituted cycloalkyl; optionally a substituted or unsubstituted aryl; optionally a substituted or unsubstituted arylalkyl; optionally a substituted or unsubstituted aromatic heterocycle; optionally a substituted or unsubstituted aromatic heterocyclic alkyl; optionally a substituted or unsubstituted nonaromatic heterocycle; optionally substituted lower alkenyl; optionally substituted lower alkylidene; -COOH; -COO-lower alkyl; -COO-lower alkenyl; -COO-lower alkylene-aryl; -COO-lower alkylene-aromatic heterocycle; carbamoyl or amino, each of which may be substituted with one or more groups selected from the group consisting of lower alkyl and cycloalkyl, each of which may be substituted with halogen, -OH, -O-lower alkyl, or -O-aryl; -NHCO-lower alkyl; and oxo.

The paragraph corresponds to p.7 of the specification except using the term "substituted or unsubstituted" instead of the optionally substituted. Please note that, the claimed or described invention is not the same invention as disclosed by the priority document because the instant invention does not allow cycloalkyl substitution while the priority documents contains Markush scope including cycloalkyl substitution.

3. Claims 5, 7, 9-13, 18-20, 22-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-10 of copending Application No. 11/593,758. Although the conflicting claims are not identical, they are not patentably distinct from each other because to the extent that cycloalkyl is not included in the scope, the non-cycloalkyl substituted material fully embraced the instant material. To the extent that cycloalkyl substitution is included as the priority documents, both the non-cycloalkyl and cycloalkyl substituted material are embraced by the copending claims. Please note that claims of overlapping subject matter in copending cases which are not a divisional of the application have been set forth by the court to be under the doctrine of obviousness double patenting. See *Pfizer Inc. v. Teva Pharm.* 86 USPQ2d 1001.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Dec. 16, 2008

/Celia Chang/
Primary Examiner
Art Unit 1625